

**HISTORICAL CONTROL DATA OF SPERM ANALYSES
FROM 2-GENERATION AND FERTILITY STUDIES
IN HsdRccHanTM: WIST, Wistar Hannover Rats**

Compiled from 2-Generation and Fertility Studies performed at RCC Ltd. Itingen/Switzerland

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Table 1: Study identification

| Study ID | Number of study | Date of performance | GEN/Seg |
|-----------------|------------------------|----------------------------|----------------|
| 1 | 842842 | 2002 / 2003 | 2- Gen. |
| 2 | 854107 | 2004 / 2005 | 2- Gen. |
| 3 | 858666 | 2005 | Seg I |
| 4 | A10934 | 2005 | Seg I |

Table 2: Sperm analysis - motility

| P-Generation | Unit | 1 | 2 | 3 | 4 |
|--------------|-------------|----|----|----|----|
| Not motile | mean | 13 | 12 | 14 | 14 |
| % | st. dev. | 5 | 3 | 6 | 8 |
| | n (litters) | 24 | 9* | 21 | 22 |
| Stat. motile | mean | 34 | 30 | 23 | 29 |
| % | st. dev. | 4 | 4 | 4 | 7 |
| | n (litters) | 24 | 9* | 21 | 22 |
| Prog. motile | mean | 53 | 58 | 63 | 56 |
| % | st. dev. | 6 | 6 | 8 | 11 |
| | n (litters) | 24 | 9* | 21 | 22 |

| F1 - Generation | Unit | 1 | 2 | 3 | 4 |
|-----------------|-------------|----|----|---|---|
| Not motile | mean | 12 | 12 | - | - |
| % | st. dev. | 4 | 4 | - | - |
| | n (litters) | 23 | 10 | - | - |
| Stat. motile | mean | 30 | 30 | - | - |
| % | st. dev. | 10 | 7 | - | - |
| | n (litters) | 23 | 10 | - | - |
| Prog. motile | mean | 58 | 58 | - | - |
| % | st. dev. | 11 | 7 | - | - |
| | n (litters) | 23 | 10 | - | - |

* = Animal No. 10: small left testis & epididymidis; excluded from summary tables

Table 3: Sperm analysis - morphology

| P- Generation | Unit | 1 | 2 | 3 | 4 |
|---------------|-------------|-------|--------|--------|--------|
| A | mean | 93.3* | 94.4** | 93.6** | 93.1** |
| % | st. dev. | 2.3 | 0.9 | 2.8 | 1.9 |
| | n (litters) | 24 | 9*** | 21 | 22 |
| B | mean | 3.2* | 1.9** | 2.81** | 2.8** |
| % | st. dev. | 1.5 | 0.6 | 2.66 | 1.5 |
| | n (litters) | 24 | 9*** | 21 | 22 |
| C | mean | 0.8* | 0.4** | 0.8** | 0.6** |
| % | st. dev. | 0.8 | 0.4 | 0.4 | 0.4 |
| | n (litters) | 24 | 9*** | 21 | 22 |
| D | mean | 2.3* | 3.0** | 2.4** | 3.0** |
| % | st. dev. | 1 | 1 | 1.2 | 0.7 |
| | n (litters) | 24 | 9*** | 21 | 22 |
| E | mean | 0.0* | 0.0** | 0.0** | 0.0** |
| % | st. dev. | 0.1 | 0.1 | 0.1 | 0.1 |
| | n (litters) | 24 | 9*** | 21 | 22 |
| F | mean | 0.4* | 0.3** | 0.4** | 0.5** |
| % | st. dev. | 0.3 | 0.2 | 0.3 | 0.3 |
| | n (litters) | 24 | 9*** | 21 | 22 |

Table 3: Sperm analysis - morphology. Cont'd

| F1-Generation | Unit | 1 | 2 | 3 | 4 |
|---------------|-------------|-------|-------|---|---|
| A | mean | 92.6* | 94.4* | - | - |
| % | st. dev. | 2.3 | 1.4 | - | - |
| | n (litters) | 23 | 10 | - | - |
| B | mean | 2.9* | 1.9* | - | - |
| % | st. dev. | 1.4 | 0.7 | - | - |
| | n (litters) | 23 | 10 | - | - |
| C | mean | 0.9* | 0.5* | - | - |
| % | st. dev. | 1 | 0.2 | - | - |
| | n (litters) | 23 | 10 | - | - |
| D | mean | 3.2* | 2.4* | - | - |
| % | st. dev. | 1 | 0.8 | - | - |
| | n (litters) | 23 | 10 | - | - |
| E | mean | 0.1* | 0.0* | - | - |
| % | st. dev. | 0.1 | 0.1 | - | - |
| | n (litters) | 23 | 10 | - | - |
| F | mean | 0.3* | 0.7* | - | - |
| % | st. dev. | 0.3 | 0.7 | - | - |
| | n (litters) | 23 | 10 | - | - |

Table 3: Sperm analysis - morphology. Cont'd

| * | ** |
|----------------------------------|--|
| A = Normal, complete sperm | A = Sperm with normal hook and tail |
| B = Normal head only (tail | B = Normal hook without tail |
| C = Complete sperm with | C = Misshapen sperm hook with tail |
| D = Complete sperm with | D = Sperm with abnormal curved hook |
| E = Complete sperm with reversed | with tail |
| F = Abnormal head only (tail | E = Sperm with reversed hook with tail |
| | F = Abnormal hook without tail |

*** = Animal No. 10: small left testis & epididymidis; excluded from summary tables

Table 4: Sperm analysis - sperm head count

| P-Generation | Unit | 1 | 2 | 3 | 4 |
|--------------|-------------|-------|-------|-------|-------|
| Cauda Epidid | mean | 657.6 | 685.7 | 591.1 | 696.8 |
| mio/g Org. | st. dev. | 76.5 | 174.6 | 54.56 | 66.58 |
| | n (litters) | 24 | 9* | 21 | 22 |
| Testis | mean | 137.1 | 139.6 | 117.7 | 134.1 |
| mio/g Org. | st. dev. | 21.68 | 14.88 | 11.32 | 15.96 |
| | n (litters) | 24 | 9* | 21 | 22 |

| F1-Generation | Unit | 1 | 2 | 3 | 4 |
|---------------|-------------|-------|-------|---|---|
| Cauda Epidid | mean | 575.5 | 652.7 | - | - |
| mio/g Org. | st. dev. | 75.96 | 126.4 | - | - |
| | n (litters) | 23 | 10 | - | - |
| Testis | mean | 115.1 | 137.4 | - | - |
| mio/g Org. | st. dev. | 11.87 | 28.31 | - | - |
| | n (litters) | 23 | 10 | - | - |

* = Animal No. 10: small left testis & epididymidis; excluded from summary tables

Table 5: Statistics sperm analysis - motility

| P-Generation | Unit | Total n | Mean | STDEV | MIN | MAX |
|--------------|-------------|---------|-------|-------|-------|-------|
| Not motile | mean | 53 | 13.25 | 0.96 | 12.00 | 14.00 |
| | n (litters) | 76 | 19.00 | 6.78 | 9.00 | 24.00 |
| Stat. motile | mean | 116 | 29.00 | 4.55 | 23.00 | 34.00 |
| | n (litters) | 76 | 19.00 | 6.78 | 9.00 | 24.00 |
| Prog. motile | mean | 230 | 57.50 | 4.20 | 53.00 | 63.00 |
| | n (litters) | 76 | 19.00 | 6.78 | 9.00 | 24.00 |

| F1 -Generation | Unit | Total n | Mean | STDEV | MIN | MAX |
|----------------|-------------|---------|-------|-------|-------|-------|
| Not motile | mean | 24 | 12.00 | 0.00 | 12.00 | 12.00 |
| | n (litters) | 33 | 16.50 | 9.19 | 10.00 | 23.00 |
| Stat. motile | mean | 60 | 30.00 | 0.00 | 30.00 | 30.00 |
| | n (litters) | 33 | 16.50 | 9.19 | 10.00 | 23.00 |
| Prog. motile | mean | 116 | 58.00 | 0.00 | 58.00 | 58.00 |
| | n (litters) | 33 | 16.50 | 9.19 | 10.00 | 23.00 |

* = Animal No. 10: small left testis & epididymidis; excluded from summary tables

Table 6: Statistics sperm analysis - morphology

| P-Generation | Unit | Total n | Mean | STDEV | MIN | MAX |
|--------------|---------------------|-----------|----------------|--------------|---------------|----------------|
| A | mean n (litters) | 374 76 | 93.60 19.00 | 0.57 6.78 | 93.10 9.00 | 94.40 24.00 |
| B | mean n (litters) | 11 76 | 2.68 19.00 | 0.55 6.78 | 1.90 9.00 | 3.20 24.00 |
| C | mean n (litters) | 3 76 | 0.65 19.00 | 0.19 6.78 | 0.40 9.00 | 0.80 24.00 |
| D | mean n (litters) | 11 76 | 2.68 19.00 | 0.38 6.78 | 2.30 9.00 | 3.00 24.00 |
| E | mean n (litters) | 0 76 | 0.00 19.00 | 0.00 6.78 | 0.00 9.00 | 0.00 24.00 |
| F | mean n (litters) | 2 76 | 0.40 19.00 | 0.08 6.78 | 0.30 9.00 | 0.50 24.00 |

Table 6: Statistics sperm analysis - morphology. Cont'd

| F1-Generation | Unit | Total n | Mean | STDEV | MIN | MAX |
|---------------|---------------------|-----------|----------------|--------------|----------------|----------------|
| A | mean n (litters) | 187 33 | 93.50 16.50 | 1.27 9.19 | 92.60 10.00 | 94.40 23.00 |
| B | mean n (litters) | 5 33 | 2.40 16.50 | 0.71 9.19 | 1.90 10.00 | 2.90 23.00 |
| C | mean n (litters) | 1 33 | 0.70 16.50 | 0.28 9.19 | 0.50 10.00 | 0.90 23.00 |
| D | mean n (litters) | 6 33 | 2.80 16.50 | 0.57 9.19 | 2.40 10.00 | 3.20 23.00 |
| E | mean n (litters) | 0 33 | 0.05 16.50 | 0.07 9.19 | 0.00 10.00 | 0.10 23.00 |
| F | mean n (litters) | 1 33 | 0.50 16.50 | 0.28 9.19 | 0.30 10.00 | 0.70 23.00 |

Table 7: Statistics sperm analysis - sperm head count

| P-Generation | Unit | Total n | Mean | STDEV | MIN | MAX |
|--------------|-------------|---------|--------|-------|--------|--------|
| Cauda Epidid | mean | 2631 | 657.80 | 47.43 | 591.10 | 696.79 |
| mio/g Org. | st. dev. | 372 | 93.05 | 55.09 | 54.56 | 174.58 |
| | n (litters) | 76 | 19.00 | 6.78 | 9.00 | 24.00 |
| Testis | mean | 528 | 132.12 | 9.87 | 117.71 | 139.61 |
| mio/g Org. | st. dev. | 64 | 15.96 | 4.30 | 11.32 | 21.68 |
| | n (litters) | 76 | 19.00 | 6.78 | 9.00 | 24.00 |

| F1-Generation | Unit | Total n | Mean | STDEV | MIN | MAX |
|---------------|-------------|---------|--------|-------|--------|--------|
| Cauda Epidid | mean | 1228 | 614.13 | 54.57 | 575.54 | 652.72 |
| mio/g Org. | st. dev. | 202 | 101.16 | 35.64 | 75.96 | 126.36 |
| | n (litters) | 33 | 16.50 | 9.19 | 10.00 | 23.00 |
| Testis | mean | 252 | 126.21 | 15.75 | 115.07 | 137.35 |
| mio/g Org. | st. dev. | 40 | 20.09 | 11.62 | 11.87 | 28.31 |
| | n (litters) | 33 | 16.50 | 9.19 | 10.00 | 23.00 |